Radiation Dose, Radiation Risk, As Low As Reasonably Achievable (ALARA) Orhan H Suleiman

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Abstract

Radiation dose limits do not exist for routine medical examinations and most clinical research since the medical benefits are always considered to be greater than the risk. It is also assumed that the radiation is "as low as reasonably achievable." In the U.S. annual radiation dose limits exist for members of the general public (1 mSv), occupational workers (50mSv), mammography (3 mGy) and fluoroscopy (10 R/m) equipment, and nuclear medicine research subjects under the authority of a Radioactive Drug Research Committee, RDRC, (30 – 50 mSv for adults, and 3 – 5 mSv for children).

Clinical and research doses range widely, with high doses exceeding the 3 mSv an individual will receive from natural background sources. The increasing complexity of imaging procedures and emerging technologies has increased the need to better understand the radiation doses patients and subjects receive. A patient undergoing a fused positron emission tomography (PET)/computed tomography (CT) procedure will receive significant doses from both the internal radioactive drug and the external x-ray based CT procedure.

Radiation doses from these various medical procedures will be compared, along with a discussion of radiation terminology. The concept of organ dose will be presented along with the International Council on Radiation Protection (ICRP) term "effective dose", which allows partial body irradiations to be compared with whole body irradiations. Current and proposed ICRP, National Council on Radiation Protection (NCRP), Nuclear Regulatory Commission (NRC), and FDA dose standards will be presented.

Introduction

The safe use of ionizing radiation, a powerful medical tool, has historically been justified because the benefit is greater than the risk. Although it is generally accepted that "...some types of cancer can result from the damage originating in a single cell...", the probability of such an event resulting in a cancer is extremely low.

The radiation protection community has developed a set of regulatory standards to protect society from the harmful effects of radiation. These range from an annual dose limit of 1 mSv (100 mrem) to a member of the general public, 50mSv (5 rem) for an occupational worker, and 500 mSv (50 rem) for emergency action.

Medical use of radiation is not subject to radiation dose limits, and human research conducted under an Investigational New Drug (IND) application is not subject to any specified limits, leaving the ultimate decision with the local Institutional Review Board (IRB). Human research conducted under the authority of a Radioactive Drug Research Committee, RDRC, which is generally recognized as safe, must limit the dose for the whole body and certain organs to 30 or 50 mSv (3 or 5 rem) for adults, and 3 or 5 mSv (300 or 500 mrem) for subjects under the age of 18.

As Low as Reasonably Achievable (ALARA)

The concept known as ALARA assumes that the user will use the smallest amount of radiation necessary to perform the medically beneficial task. This implies that (1) the user knows how much radiation an individual is receiving, and (2) has a knowledge of the medical benefit associated with the radiation related task.

Comparisons of almost any nature involve an objective and usually quantitative measure. Radiation dose is an important intermediary metric for risk, but it's determination is not simple.

Entrance Exposure (Air Kerma)

A practical radiation metric is exposure, ionization per unit mass, originally defined as 1 electrostatic unit of charge per cc of air. The value of exposure is that it is a measurable metric. This is important for radiation safety assessment, where the intensity of a radiation source needs to be known by health physicists or first responders. Radiation exposure using the international system of units (SI) is reported as air kerma, and corresponds to the amount of energy absorbed in air. Air kerma, which represents ionization but is also expressed as a unit of dose, is clearly different than the absorbed dose to an organ, although both terms are the same. This can be confusing.

Exposure is converted to absorbed dose in air using traditional units of Roentgen and rad:

IR x 0.869 rad/R = 0.869 rad ~ 1 rad (1 significant figure)

Radioactivity

The traditional measurable metric for radioactivity is the Curie, originally defined as the amount of radioactivity in 1 gm of radium. This corresponds to 3.7 x 10¹⁰ disintegrations per second. The SI unit is the Becquerel, which is 1 disintegration per second. One Ci is therefore 3.7 x 10¹⁰ Bq.



Radiation Dose - The Physical Unit

The fundamental physical concept is energy absorbed per unit mass, or radiation absorbed dose, the rad.

1 rad = 100 ergs/gm, the SI unit is the Gray, 1 Gy = 1 Joule/kilogram (1 Gray = 100 rads).

Radiation Dose - The Biological Unit

The Gray (rad) is a physical unit, but 1 Gray (rad) of energy can be deposited within a mass of tissue using different types of radiation, such as photons, electrons, neutrons, and alpha particles. The resulting biological effects may vary. For most nuclear medicine and x-ray examinations the radiation weighting factor is 1, consequently the terms Gray (rad) and Sievert (rem) are used interchangeably. The biological equivalent of dose for a specific tissue or organ is Equivalent Dose, H_T, and is equal to the dose in Gray (rads) multiplied by a radiation weighting factor, w_r, which accounts for the relative biological effect (RBE) of the different types and energies of radiation. The SI unit for equivalent dose is the Sievert, rem is the traditional unit.

Equivalent Dose H_T = Dose x radiation weighting factor (W_R) Relates physical quantity to biological end-point

Type and energy	w _R (RBE)*
Photons - all energies	1
Electrons - all energies	1
Neutrons	5 – 20
Protons, > 2 MeV	5
Alpha particles	20

* Relative Biological Effectiveness 100 rem = 1 Sievert

Organ (Tissue) Doses

The single most important metric for risk assessment is the organ dose. Once you know the actual organ dose, you can definitively derive the risk to the patient for the specific associated cancer, e.g. leukemia with bone marrow dose, or thyroid cancer with the thyroid dose. Organ dose tables, derived from Monte Carlo computer calculations, are available which relate the input values of air kerma for x-ray or radioactivity for nuclear medicine, with the output being organ doses.

The Homogenized Single Figure of Merit for Radiation Dose

In order to relate partial body irradiations to a whole body dose the ICRP, in 1977, introduced the concept of effective dose equivalent to the whole body, H_{wb} . It did this by introducing tissue weighting factors, W_{τ} , for different tissue. Each individual tissue or organ dose, H_{τ} is multiplied by a unique tissue weighting factor, so that the sum of these is nominally equivalent to radiation risk associated with a uniform whole body dose. H_{wb} . This is described by the following expression:

$$\sum_{T} W_{T} H_{T} = H_{wb}$$

In 1991, ICRP Report 60 changed these tissue weighting factors, and replaced the Effective Dose Equivalent, H_{wb} , with Effective Dose, E.

$$\sum_{\tau} W_{\tau} H_{\tau} = E$$

Effective dose, E, similar to effective dose equivalent, H_{wb} , also allows one to relate partial body irradiations (individual organ or tissue doses, or limited x-ray fields) to a uniform whole body irradiation. This comparison is extremely useful for relating relative risk to patients or human research subjects, especially when obtaining informed consent.

Currently, in the United States, the Nuclear Regulatory Commission regulations are based on the ICRP 26 guidance. The ICRP 26 and ICRP 60 tissue weighting factors are listed below, along with the proposed 2005 tissue weighting factors.:

Tissue Weighting Factors (w_t)

Organ (Tissue)	ICRP 26	ICRP 60	ICRP Draft 2004
Gonads	0.25	0.20	0.05
Breast	0.15	0.05	0.12
Red BM, Lung	0.12	0.12	0.12
Thyroid	0.03	0.05	0.05
Bone Surfaces	0.03	0.01	0.01
Colon, Stomach	NC	0.12	0.12
Bladder, Liver, Esophagus	NC	0.05	0.05
Skin	NC	0.01	0.01
Salivary glands, Brain	NC	NC	0.01
Remainder	0.30	0.05	0.10
TOTAL	1.00	1.00	1.00

NC = Not considered individually in this report, included under remainder.

Radiation Dose, (E) from a Variety of Sources

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Radiation Source	Effective Dose (E)	Equivalent to # of chest x-rays	Equivalent time from atural background radiation	
		Natural Background		
U.S. 1 year	3 mSv	150	1 year	
		Medical Examinations		
		X-ray		
Chest x-ray Mammo (1 view) CT-head Upper GI fluoro CT-abdomen Tc-99m-lung perf Te-99m – bone PET-FDG	0.02 mSv 0.09 mSv 2 mSv 3 mSv 10 mSv	1 4.5 100 150 500 Nuclear Medicine 50 200 500	2.4 days 11 days 8 months 1 year 3.3 years 4 months 1.3 years 3.3 years	
		Regulatory Limits		
RDRC-adults RDRC-subjects < 18	50 mSv 5 mSv	2,500 250	16.7 years 1.67 years	
Member Gen Pop Occupational Limit Emergency Worker	1 mSv 50 mSv 500 mSv	50 2,500 25,000	4 months 16.7 years 167 years	

Medical Benefit versus Risk

If an individual receives an effective dose of 10 mSv (1 rem) from a high dose medical exam, (s)he receives an additional risk of dying from cancer of 0.001 to 0.0001 during her/his lifetime (assuming a factor of 10 uncertainty in risk estimation). If the annual mortality rate from cancer is 0.229 (22.9%) without the benefit of the exam, then with the benefit of the exam (and assuming the lifetime risk is equivalent to the annual risk for this calculation), the risk of dying from cancer increases from the natural mortality rate of 22.90% to 22.91% (lower estimate) or 23.00% (upper estimate). This additional relative risk is clearly difficult, if not impossible, to detect above natural cancer mortality.

If a population of 1,000,000 patients each receive 10 mSv effective dose, their collective life- time risk is 1,000,000 x 0.0001 (or 0.001) which corresponds to 100 (or 1,000) lifetime cancer deaths.

The medical benefits clearly outweigh the radiation risk of most medical examinations. However, the perception of risk changes when estimated for an individual, when the medical benefit of the examination is understood, compared to the risk when addressing large populations.

In Summary

The benefits of <u>necessary</u> medical examinations are almost always greater than the radiation risk. Although radiation is a carcinogen, it's medical benefit has always been greater than the risk of inducing cancer. However the safe use of radiation has always assumed the concept of ALARA, which implies that knowledge of the actual radiation dose to an individual must be known.

References

ICRP Publication 26 (Annals of the ICRP Vol. 1 No. 3, 1977) Recommendations of the International Commission on Radiological Protection.

ICRP Publication 60 (Annals of the ICRP Vol.21 No. 1-3, 1992) 1990 Recommendations of the International

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Title 10 Code of Federal Regulations Part 20 Standards for Protection Against Radiation

Title 21 Code of Federal Regulations Part 361.1 Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded:Drugs Used in Research. Radioactive Drugs for certain research uses.

Title 21 Code of Federal Regulations Part 900 Mammography



